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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,669	09/21/2001	Michael Garabedian	GARABEDIAN=1.1A	5735

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BROWDY AND NEIMARK, P.L.L.C.  
624 Ninth Street, N.W.  
Washington, DC 20001-5303

EXAMINER
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AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 01/2/04

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/816,669		GARABEDIAN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ramin (Ray) Akhavan		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 16-18, 21-26 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 19, 20, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II on 12/03/03 is acknowledged. The traversal is on the ground(s) that Groups XIV and XXII should be considered for examination, because applicant asserts that these groups are not a separate and distinct invention, viz., Group II. This is found persuasive, thus Groups II and XIV will be examined, i.e. claims 14, 15, 19, 20, 27 and 28. All other claims are withdrawn from consideration. With regard to Group XXII (claims 31 and 32), where applicable, process claims will be rejoined and examined only if the product claims subject to restriction requirement are deemed allowable.

### ***Drawings***

New corrected drawings are required in this application because Fig. 13A and B are illegible. In addition all figures appear to be slanted viz., position on the page. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: the description of Fig. 2 refers to a single figure, but the drawings include two figures titled Fig. 2. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 14, 15, 19, 20, 27 and 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 14, 19 and 20 recite the limitation "activity" of SEQ ID NO: 4. There is insufficient antecedent basis for this limitation in the claim. In claim 14, the preamble recites that the isolated protein "interacts with androgen receptor to regulate androgen-dependent gene expression". For there to be proper antecedent basis, subsequent claims need to refer to the particular "activity" applicant is claiming.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claim 14, 15, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

The claims are drawn to the protein with the amino acid sequence of SEQ ID NO: 4, which interacts with androgen receptor to regulate androgen-dependent gene expression. In addition the claims are drawn to a protein with 85 percent identity to the sequence of SEQ ID NO: 4 with the activity of the same, as well as fragments of SEQ ID NO: 4 having the same activity. These are genus claims with regard to any 85 percent homologous or other fragment of SEQ ID NO: 4 having the activity of the protein described by SEQ ID NO: 4.

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

The specification does not contain any examples of such fragments having any such activity, whether interaction with the androgen receptor or enhancing an androgen-receptor-dependent response. The specification does teach that of eight fragments tested, none interacted with the androgen receptor. (e.g. Spec. at 58). In addition the specification teaches that for the single fragment tested, viz., affecting androgen receptor transcription activity (i.e. ART 27: 1-127), there was no effect. One of ordinary skill in the art cannot envision all fragments of SEQ ID NO: 4 claimed, because the disclosure is not descriptive of the complete structure of a representative number of species.

In sum it must be considered that applicant has not disclosed a representative number of species sufficient to convince the skilled artisan that applicant is in possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**3. Claims 14, 15, 19, 20, 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al. (Application No. US 2003/0027999 A1) (hereinafter *Rosen*) (claiming priority to U.S. Provisional 60/134,068 filed 05/13/1999).**

Claims 14, 15, 19, 20, 27 and 28 are drawn to a protein encoded by SEQ ID NO: 4 or proteins fragments comprising SEQ ID NO: 4 that have the same activity. In addition the claims are drawn to antibodies specific for the protein encoded by SEQ ID NO: 4.

*Rosen* teaches a protein encoded by SEQ ID NO: 179, which is the same sequence as applicant's SEQ ID NO: 4. Therefore all claims that are drawn to protein encoded by SEQ ID NO: 4 or proteins that comprise SEQ ID NO: 4, are anticipated (i.e. claim 14, 15, 19, 20). In addition, *Rosen* teaches production of antibodies specific for the protein taught. (*See e.g.*, [1929]-[1937]).

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

  
GERRY LEFFERS  
PRIMARY EXAMINER